



# **An Brief Overview – Medtronic Wireless Medical Applications**

## **Prepared for:**

**U.S. Federal Communications Commission**

**U.S. Food and Drug Administration**

**Public Meeting, July 26-27, 2010**

**Enabling the Convergence of Communications and Medical Systems**

***Session 1: Current State of Wireless Health and Lessons Learned***

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**July 26, 2010**

# Introduction

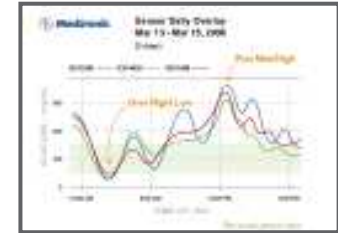
- Medtronic employs wireless technology in a large number of products today
  - Medtronic-proprietary air interface standards
  - Industry-standard network interfaces: WiFi™, GSM, etc.
  - Frequency bands include inductive (low frequency), ISM, and MedRadio (no “one size fits all” solution)



# Medtronic MiniMed Paradigm® REAL-Time Revel™ System



*The pump can numerically and graphically display wirelessly transmitted data from a continuous glucose sensor.*



*The pump has the ability to wirelessly download pump data to a PC for retrospective analysis of therapy.*



*The pump can wirelessly receive and store blood glucose measurements from a paired blood glucose meter.*



**Paradigm® Insulin Pump**



*The pump can wirelessly receive commands from a remote control device.*

# Medical Device Radiocommunications Service (MedRadio) Review

- **Evolved from the Medical Implant Communications Service (MICS) 402-405 MHz “core” band rules**
  - MICS introduced in July of 1995 to FCC
  - Collaborative effort with FCC/NTIA
  - Petition for Rule Making filed 1997 with FCC
    - Healthcare professionals, physicians and industry participated in FCC process
- **MICS Report and Order issued in Nov. 1999**
- **MedRadio Report and Order issued in March 2009**
  - MICS “core” band rules reaffirmed
  - “Wing” band (401-402/405-406 MHz) rules adopted; generally aligned with published ETSI Medical Data Services (MEDS) standards.

# MedRadio 402-405 MHz “core” band usage scenarios



## Implant

- Streamlined implant procedure
- Removes the inductive antenna from the sterile field
- Real-time communication of critical data



## In-office

- Complete wireless follow-up
- Improved comfort for patient



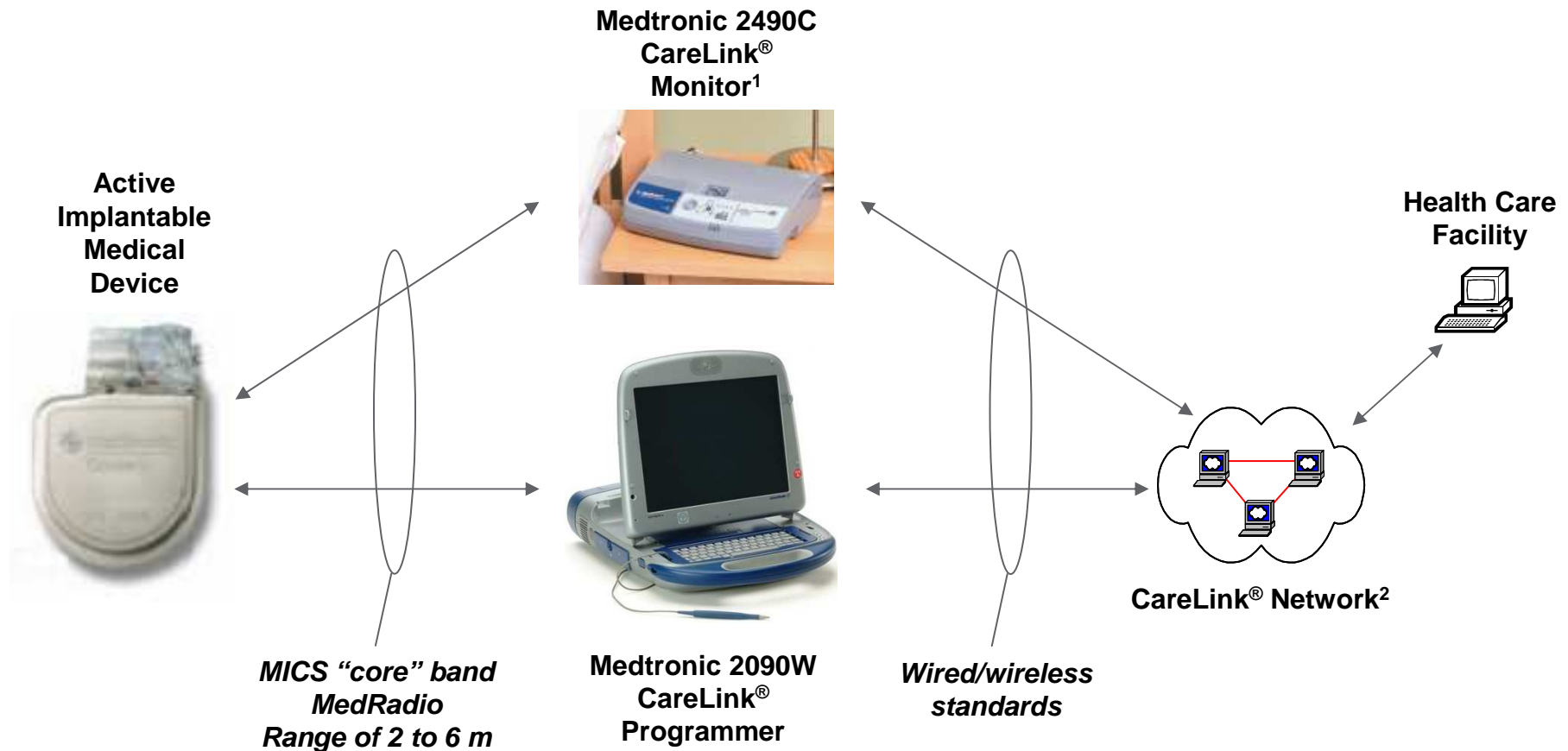
## Remote

- Pre-scheduled device checks
- Replaces regularly scheduled clinic visits
- Physician selected alert conditions



# Medtronic Conexus® Wireless Telemetry System

- Over 300,000 wireless implants worldwide



<sup>1</sup>Optional Medtronic M-Link™ Cellular Accessory available (launched May 10, 2010).

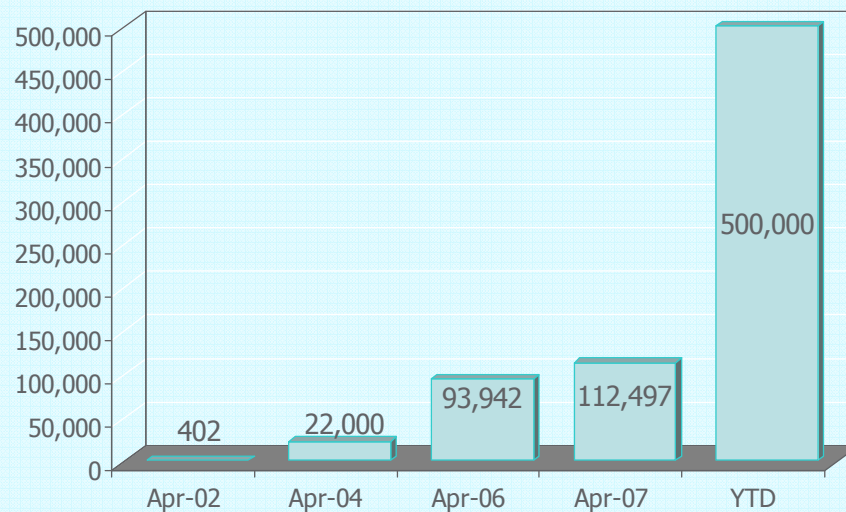
<sup>2</sup>The Medtronic CareLink® Network is a remote monitoring service for implantable cardiac device patients, with more than 4,000 clinics and 500,000 patients enrolled in 31 countries. The CareLink® Network has registered more than two million patient data transmissions since the service's inception in 2002 (source: CareLink® metrics database).

# Medtronic M-Link™ Cellular Accessory & Remote Follow-up Trends

## CareLink® Network Trends

As demand for the CareLink Network continues to increase, so does the need for cellular connectivity<sup>1</sup>

Patients Enrolled on CareLink (July 2010)



<sup>1</sup>Medtronic data on file

## Lessons Learned

- ITU-R Recommendation SA.1346 (1998) (revised to RS.1346) was key to worldwide adoption of the MICS band
  - Over fifty-five countries worldwide
  - International harmonization; regulations with the same basic parameters have been adopted in all major regions of the world

Rec. ITU-R SA.1346

RECOMMENDATION ITU-R SA.1346

SHARING BETWEEN THE METEOROLOGICAL AIDS SERVICE AND  
IMPLANT COMMUNICATION SYSTEMS (MICS) OPERATING IN  
MOBILE SERVICE IN THE FREQUENCY BAND 401-406 MHz

(Question ITU-R 144/7)

### 信息产业部司局

信无函〔2007〕90号

#### 关于增加400MHz频段微功率（短距离） 无线电应用工作频率的通知

各省、自治区、直辖市无线电管理办公室（局）：

为促进微功率（短距离）无线电技术的发展，满足社会需求，根据我国频率划分和使用情况，经研究，为生物医学遥测微功率（短距离）无线电应用增加402—405 MHz工作频率。具体事宜通知如下：



## Lessons Learned

- Radio spectrum decisions have long-term consequences for patients
  - For medical devices, the product life cycle is much longer than for consumer products
- Listen Before Transmit (LBT) and Adaptive Frequency Agility (AFA) techniques have been proven effective for establishing high reliability communication links
  - Including mitigation of interference from the primary user (meteorological aids) in the 401-406 MHz band
- Network infrastructure and trends
  - Telecommunications network infrastructure must be adequately scoped to accommodate an increased level of remote monitoring and migration from PSTN to cellular